

REMARKS

Claims 28-39, 46-48 and 74 are in this application. Claims 1-27, 40-45 and 49-73 have been cancelled.

Applicants preserve all rights to file one or more divisional applications for any subject matter disclosed in this application and not presently claimed.

The claims were rejected under 35 USC 103(a) as allegedly being unpatentable over AU-A-63136/94 and WO 97/16977 both in view of Clark et al. and newly Ballard et al. (US patent 6,319,522). Applicant respectfully traverses this rejection and submits that the references do not set forth even a *prima facie* case of obviousness for the invention as now claimed.

Contrary to what the Examiner asserts, there is no combination of the references either alone or in combination that disclose or suggest a method of changing the physical work capacity of a subject by administering to the subject a food composition containing a colostrum fraction prepared as defined in claims 28 and 74. As described on page 3 of the specification, physical work capacity is a measure of the ability to do physical work including any exercise performance, recovery after exercise and reduction of fatigue. On page 44 of Clarke et al. it is stated that a single exhaustive workout is followed by a temporary immune depression and that colostrum's many immune factors demonstrate a significant reduction in the occurrence and severity of numerous types of infections caused by physical and emotional stress. This does not disclose or suggest that a method of changing physical work capacity. The specification of this application includes examples of how to monitor changes in physical work capacity, performance of endurance athletes, and power and strength of athletes. There is no disclosure or suggestion in Clarke or in any other of the references cited by the Examiner of these benefits.

In addition, Clarke et. al. teaches away from the claimed invention. According to the second to last paragraph on page 15, it is emphasized that the effectiveness of the colostrum depends on its quality and how it is processed. Clarke et al. teaches that higher percentages of

immunoglobulins actually diminish colostrum's effectiveness in combating infection. Their conclusion is that the most effective colostrum is that which is gently processed, but otherwise left with the balance of its immune and growth factors as nature intended. Therefore, one would assume from this statement that highly processed colostrum is not effective. The colostrum of the present invention has positive effects on physical work capacity.

On page 16, Clarke describes how to process and obtain high quality colostrum. According to point 5. The colostrum should be filtered and homogenized to break down the long-chain proteins (immunoglobulins) for better assimilation. The colostrum prepared and used according to the invention is not homogenized.

Clarke et al. discloses that not all colostrums function in the same way. The effect achieved by the colostrum depends on how it is processed. The process used to prepare the colostrum fraction of present invention is not disclosed nor suggested by Clarke et al. and therefore, it is not obvious that the colostrum prepared as defined in the claims would have an affect on physical work capacity of a subject.

Ballard et al. disclosure of reconstituting freeze dried powder of colostrum is irrelevant to the claimed invention. According to claims 28 and 74, the colostrum retentate fraction is spray dried. Spray drying is different process than freeze drying. As described in example 1 of this application the concentrate is spray dried in an aseptic, pharmaceutical model 2 stage spray drier with a filtered air supply to produce colostrum powder.

While AU-A-63136/94 and WO 97/16977 describe methods for processing of colostrum, there is no disclosure nor suggestion in the combination of references cited by the examiner for a method of changing physical work capacity of a subject by administering colostrum as prepared as defined in the claims of this application.

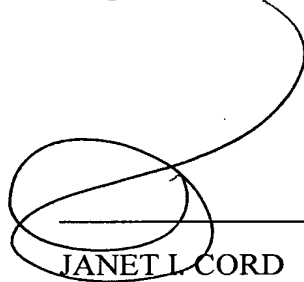
The claims presently on file are all directed to methods for changing physical work capacity, and all recite an administering step which is ingestion.

The methods claimed in this application are not obvious over the combination of references cited by the examiner.

The certified copy of the priority application PP3271 will be filed.

In view of the above, it is respectfully submitted that all rejections and objections of record have been overcome and that the application is now in allowable form. An early notice of allowance is earnestly solicited and is believed to be fully warranted.

Respectfully submitted,



A handwritten signature in black ink, consisting of a large, stylized 'C' that loops around and crosses itself, positioned above a horizontal line.

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